

C-3362/0/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Nadkarni, S. *et al.*) ATTORNEY DOCKET NO.: C-3362/0/US
SERIAL NO.: 09/731,349) GROUP ART UNIT: 1615
FILED: December 6, 2000) EXAMINER: S. Oh
TITLE: VALDECOXIB COMPOSITIONS
DATE: August 19, 2002

CERTIFICATE OF MAILING

I hereby certify that this Response to Office Action is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on August 19, 2002.

Luisan B. Sawilek

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

RESPONSE TO OFFICE ACTION DATED JULY 16, 2002

This communication is responsive to the Office Action dated July 16, 2002 in the above-referenced application. Response is made within the three months shortened statutory period for reply set in the Action and no fee is believed payable in respect of this communication.

However, if it should be determined that a fee is payable, authorization is hereby given to charge such fee to Deposit Account No. 19-1025.

The Action acknowledges receipt of Information Disclosure Statements received on January 5, 2002 and April 15, 2002. Applicant respectfully requests initialed copies of Forms PTO-1449 confirming that documents submitted with these Information Disclosure Statements have been considered.

The Examiner's attention is also respectfully drawn to Applicant's Letter dated July 19, 2002, submitted too late to be considered in the present Action, and requests that it be considered prior to issuance of the next office action.

Claims 1, 3 and 5-18 are pending in the application. Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph as "being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention". Office Action, paragraph 4. This rejection is respectfully traversed.

In a telephone conversation with the Examiner on August 16, 2002, it was gathered by the undersigned that the "indefiniteness" ascribed to Claim 1 arises from confusion as to whether Applicant intends to claim a composition or a method of administration.

Applicant confirms that Claim 1 is drawn to a pharmaceutical composition. Reference to oral administration in Claim 1 is part of a recitation of a property of the composition that defines the composition in functional terms. This property is set forth as a test that can be conducted to determine whether or not a composition falls within the scope of the claim.

Parsing Claim 1, the claim is seen to be drawn to a pharmaceutical composition defined by the following elements:

- A. the composition comprises valdecoxib;
- B. the valdecoxib is in particulate form;
- C. the valdecoxib is in an amount of about 5 mg to about 40 mg per dose;
- D. the composition further comprises one or more pharmaceutically acceptable excipients; and
- E. the composition has a pharmacokinetic (PK) profile such that it passes the following test: when a single oral administration of the composition, in an amount containing about 20 mg of valdecoxib, is given to a fasting subject, the subject's blood serum concentration of valdecoxib reaches 20 ng/ml not later than about 0.5 h after administration.

It will be noted that the dosage amount of about 20 mg used in the test does not limit the amount of valdecoxib in the composition, which can be from about 5 to about 40 mg. For example, in the case of a 10 mg tablet, the test calls for two such tablets to be administered to determine whether the tablet is embraced by the claim. Similarly, in the case of a 40 mg tablet, the test calls for half a tablet to be administered.

It will further be noted that the test of element E calls for administration of "about 20 mg", not a "minimum of 20 mg", as indicated in the Action.

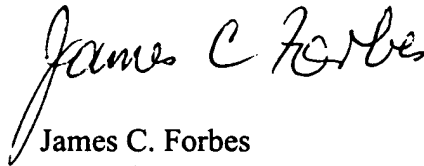
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It will still further be noted that 20 ng/ml (not "20 mg/ml" as indicated in the action) is not a concentration in the pharmaceutical composition claimed but in blood serum of a subject to whom the claimed composition is administered in the test of element E.

Applicant believes, as demonstrated by the parsing above, that Claim 1 as presently worded is not indefinite. However, Applicant is willing to amend the claim further to render the claim even clearer, and respectfully requests the Examiner to contact the undersigned by telephone at the number given below with any suggestion he may have that would accomplish this.

The present application is believed to be in condition for allowance.

Respectfully submitted,



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